

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: IMPELLIZZERI, Frederic

SERIAL NO.: 10/530,683

ART UNIT: 3733

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EXAMINER: Kim, John

TITLE: SELF-LOCKING OSTEOSYNTHESIS DEVICE

Amendment B: REMARKS

Upon entry of the present amendments, previous Claims 10 - 18 have been canceled and new Claims 19 - 27 substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of distinguishing the present invention from the prior art.

In the Office Action, it was indicated that Claims 10 - 11, 13 - 16 and 18 were rejected under 35 U.S.C. § 102(c) as anticipated by the Hawkes patent. Claim 12 was rejected as being obvious over the Hawkes patent. Claim 17 was rejected as being obvious over the Hawkes patent in view of the Bono patent.

As an overview to the present reply, independent Claims 19 and 26 have each been revised so as to incorporate certain limitations which were not shown nor suggested by the Hawkes patent. In particular, the inserts are now recited as "fixedly and non-rotationally" received in the "plurality of openings". The bone screws are now positively recited in independent Claim 19. The biocompatible polymeric material is identified as "suitable for allowing a self-tapping of the smooth wall of the hole with the threads" of the bone screws. Independent Claim 19 further indicates that the bone screw has a head that is locked in the plurality of inserts when the thread of the bone screws engages an underlying surface. Application respectfully contends that these features serve to

distinguish the present invention from the prior art patents.

The present invention obtains specific results that are neither shown nor suggested by the device of the Hawkes patent. The present invention relates to a self-locking osteosynthesis or osteotomy device of the type having a plate with an appropriate shape designed to be affixed on bone fragments. A screw is used so as to ensure the connection of the plate to the bone fragments. The cooptation of the bone fragments by using plates and screws are often utilized in bone surgery or orthopedic surgery. In order to obtain proper results, it is important that the plates or implants are screwed permanently to the bone fragments. As such, it is important that the screws cannot unscrew and move back so as to prevent any displacement of the implants relative to the bone fragments. However, on the other hand, it is often be desirable to be able to choose the orientation of the screws relative to the plates as a function of the positioning and the shape of the fragments to be assembled. As such, the quality of the assembly is greatly improved.

The present invention and the device of the Hawkes patent do not relate to the same field of orthopedic surgery. The device of the Hawkes patent is for spinal fixation surgery and not for the assembly of bone fragments. The Hawkes patent would not be a plate having very small dimensions and of a thickness of less than 1mm.

Application respectfully contends that the Hawkes patent does not anticipate new independent Claims 19 and 26. In particular, new independent Claim 10 specifies that the inserts are fixedly and non-rotationally received in the openings. In contrast, in the Hawkes patent, the inserts (receiving member 46) are housed rotationally in the holes (62) of the plate. In particular, independent Claim 1 of the Hawkes patent recites that "said receiving member is configured and dimensioned relative to the first opening of the elongate member to remain movable within said first

opening after implantation in a semiconstrained manner."

As such, the language "fixedly and non-rotationally" should distinguish the present invention from the Hawkes patent. Additionally, independent Claims 19 and 26 also specify that the bone screw head is threaded and that the head of the bone screw can self-tap into a periphery of the smooth wall of the hole and is locked in the inert when the thread of the bone screw engages an underlying surface. In other words, the mechanical bond between the screw and the plate is achieved through self-tapping of the insert. As such, the screw head has, for that purpose, a tapered or conical thread. In contrast, in the Hawkes patent, there is mechanical bond between the screw and the plate through the use of inserts (receiving member 64). This mechanical bond is created by friction (see column 13, lines 46-50). The head of the screws of the Hawkes device has only one smooth tapered surface 72 which fits into the tapered hole (66 - 68) of the inserts (receiving member 64). As such, the Hawkes patent does not teach the structure of the present invention as defined by independent Claim 19 and 26.

Specifically, relative to independent Claim 26, Applicant notes that the method illustrated in Figure 5 of the Bono patent shows the screws 18 as having a threaded tapered head (70). However, this threaded tapered head is intended to work together with a mobile insert (bushing 16) which has a pre-existing internal screw thread (38) and which was produced at the time of the manufacture. The insert does not have a smooth wall. As such, unlike the present invention, the screws engage the threads on the insert. The present invention utilizes the threading of the screw to create its own threading in the insert. Applicant respectfully contends that there is no teaching to suggest why the Hawkes patent and the Bono patent can be combined, in any way, so as to show the teachings of the present invention. In fact, it is extremely difficult to see how the Bono patent can

be combined, in any way, with the teachings of the Hawkes patent

Based upon the foregoing analysis, Applicant contends that independent Claims 19 and 26 are now in proper condition for allowance. Additionally, those claims which are dependent upon these independent claims should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

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